APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,767	02/06/2004	Jacob W. Mandema	021720-001310US	5592

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EXAMINER
MILLER, MARINA I

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/773,767	MANDEMA ET AL.
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>08 November 2004</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-28</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-28</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>06 July 2004</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

    1.☐ Certified copies of the priority documents have been received.

    2.☐ Certified copies of the priority documents have been received in Application No. _____.

    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
    application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date <u>7/27/04;11/8/04</u>.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Claims 1-28 are pending. Claims 1-28 are presently under examination.

Priority

Applicant has not complied with one or more conditions for receiving the benefit

of an earlier filing date, U.S. provisional application 60/511,602 filed 10/14/2003 under

35 U.S.C. 119(e) for claims 1-44. Claims 1-28 are drawn to a method and a system for

representing performance of a drug candidate comprising steps of receiving raw data,

extracting index information, referencing information to generate a metadata file,

referencing the metadata file to convert raw data into a binary file, generating a user

interface comprising a menu, presenting the menu to a user, receiving a user input,

causing the interface to reference and identify a subset of the binary file, and presenting

the data subset. The steps of referencing information to generate a metadata file,

referencing the metadata file to convert raw data into a binary file, and causing the

interface to reference and identify a subset of the binary file are not supported by the

provisional application 60/511,602. Also, the limitations recited in claims 2-28 are not

supported by the provisional application 60/511,602.

If applicant desires benefit of these provisional applications, applicant is invited to

point to specific support by page and line number for each limitation of instant claims in

the provisional application mentioned above. Priority for claims 1-28 is granted only to

the filing date of the instant application filed 02/06/2004.

Information Disclosure Statement

Information Disclosure Statements (IDS) filed 7/27/2004 and 11/08/2004 have

been considered in full.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of
matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the
conditions and requirements of this title.

Claims 1-28 are rejected under 35 U.S.C. 101 because the claimed invention lacks

patentable utility.

Claims 1-25 are directed to a method and system for representing performance of

a drug candidate. The specification on p. 4 states that there is a need in the art for systems

for modeling the behavior of drug candidates wherein different knowledge is used for

developing a model of compounds' clinical safety, tolerability, and efficacy profile in

relation to the compounds' competitors. Further, knowledge contained in those models is

broadly accessible to the clinical development organization. The specification also states

on p. 7-8 that Drug Model Explorer software may be utilized to facilitate decision-

making regarding clinical development programs for particular drugs. The claims do not

recite model development nor decision-making. The "result" of the claimed method is

presenting a subset of a binary file relevant to a user-selected input wherein the binary

file is obtained by conversion of raw data generated by a drug candidate behavior model.

In order for the result of the method (*i.e.*, a data subset of a binary file) to be used for

decision-making regarding clinical development of a drug candidate, one skilled in the art

must be aware of some correlation between the information received (a subset of data)

and condition or disease for which the drug is selected, or between the model output (*e.g.*,

drug behavior) and condition, disease, *etc.* Absent any disclosure of a correlation between the model/data, the drug under evaluation, and some disorder/disease to be treated, there is no immediate benefit to a member of the public for performing the method, and hence, there is no utility for the method. No such information is recited in the instant claims; further research would be required to determine such a correlation. Applicant is reminded that a "use" to perform further research is not a utility under 35 U.S.C. 101.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "raw data generated by a model." It is not clear whether "generation" of raw data is intended to be an active, positive method step.

Claim 1 recites a metadata file "explicitly reflecting a hierarchical structure model." The limitation "explicitly reflecting" is not clear and neither claims nor the specification defines the limitation.

Claim 1 recites the limitation "referencing" index information and metadata. It is not clear what steps are actually intended and whether "referencing" is intended to mean using, referring, generating, or linking, *etc.* or, as defined by Merriam-Webster Dictionary: citing, supplying with a reference, or putting in form adapted to easy reference. Claim 1 recites the limitation "causing the interface to reference the metadata

file." It is further unclear whether "to reference" is intended to be an active, positive

method step of the method and whether "referencing" the metadata is intended to mean to

inquire, link, use, refer, *etc.*

Claim 1 recites referencing index information "to generate a metadata file." It is

not clear whether "generation" of the file is intended to be an active, positive method

step.

Claim 1 recites the limitation referencing a metadata file "to convert the raw

data." It is not clear whether "conversion" is intended to be an active, positive method

step.

Claim 1 recites the limitation "to identify a subset." It is not clear whether

"identification" of a subset is intended to be an active, positive method step.

Claim 1 recites a binary file "relevant" to a user-selection. The metes and bounds

of the "relevancy" of a binary file to a user selection are not clear. One skilled in the art

would not know how to determine (*i.e.*, specific criteria) whether a binary file is

"relevant" to a user-selection and neither claims nor the specification define establishing

relationships between a user-selection and a binary file.

As the limitations recited in claim1 are not clear, as set forth above, claim 1 is

indefinite. Claims 2-25 depend from claim 1, and are therefore indefinite.

Claim 4 recites the limitation "to one of." It is not clear whether "to one" relates

to a subset, a value, a clinical effect, user-defined value, *etc.* As the intended limitation is

not clear, claim 4 is indefinite.

Claim 5 recites the limitation "to fall <u>one of</u>." It is not clear whether "one of" is

related to a clinical effect that falls in one of three categories: within, above, and below a

user-defined range, or alternatively, "one" is related to one value or one effect that falls

within, above and below the defined range. As the intended limitation is not clear, claim

5 is indefinite.

Claim 26 recites the limitation "to reference" metadata. It is not clear whether

"reference" metadata is intended to mean inquire, link, use, refer, *etc.*, as set forth above.

Claim 26 recites the limitation a binary file "relevant to" inputs. The metes and

bounds of the "relevancy" of a binary file to a user selection are not clear. One skilled in

the art would not know how to determine (*i.e.*, specific criteria) whether a binary file is

"relevant" to a user-selection and neither claims nor the specification define establishing

relationships between a user-selection and a binary file.

As the limitations recited in claim26 are not clear, as set forth above, claim 26 is

indefinite. Claims 27-28 depend from claim 26, and further indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 13-22, 24-26, and 28 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Fink, U.S. Patent 5,808,918, in view of Watkins, U.S. Patent

6,457,017.

Fink discloses a method and a system for modeling biological systems and disease processes. Fink's invention provides an interactive tool to help identify new drug targets (col. 3, line 7-23; col. 7, line 34-38). Fink discloses building a model based on knowledge from literature, books, experiments, internal information, clinical trials, *etc.* (col. 7, line 40-67) and using the model to generate raw data (col. 12-13, *Model Uses*). Fink discloses obtaining raw data comprising index information (fig. B; col. 9, line 5-14; col. 12, line 58-67), treatment scenario (col. 12, line 58-67; col. 13, line 30-33), and output performance information type (*e.g.*, effect on the immune system, col. 12, line 52-57). Fink discloses extracting index information from raw data (fig. 3 and col. 12-13, bridging paragraph). Fink discloses generating a user interface wherein a user may input his selection of data and "interact" with a model (col. 5, line 48 – col. 6, line 3; col. 6, line 62-67). Fink discloses presenting a menu to a user (*see* fig. 3 and col. 5, line 48-65). Fink discloses receiving a user input at the interface (col. 5, line 48-65; col. 12, line 49-50; col. 13, line 27-36). Fink discloses hierarchical structure of the model (col. 4, line 37-57; col. 10, line 1-23) wherein fundamental model units represent relevant biological information and processes at each level. Fink discloses that output is obtained according to a user selection (input) and presented as a data subset in a graphic user interface (col. 5, line 57 – col. 6, line 3; col. 13, line 26-34). Fink discloses data representing clinical effect (col. 12, *Model Uses*). Fink discloses an independent variable required for a clinical effect (*e.g.*, bacterial load, col. 12, line 46-57). Fink discloses a probability of distribution (col. 9, line 9-32). Fink discloses input uncontrollable variables (family history, patient is a smoker) (col. 13, line 26-30). Fink discloses controllable variables (treatment regimen, col. 13, line 32-34). Fink discloses endpoint based on a clinical measured value (col. 13,

line 32-34). Fink discloses that uncontrollable variables comprise a model assumption

(using model for particular patients), col. 13, line 26-37. Fink also discloses a system for

executing his method because it is a computer method (fig. 9 and col. 13).

Fink does not disclose metadata files, binary files, and converting raw data onto a

binary file by referencing a metadata file.

Watkins discloses an information management system. Watkins' system has an

object-oriented architecture over a relational database in order to manage files of

information wherein files are indexed and can be retrieved (*see* abstract). Watkins

discloses a graphical user interface for displaying files content to a user (col. 11-12, *User*

Interface). Watkins discloses that raw data are indexed and stored in a database and

converted to a specified type of data by the system to a human-readable form (col. 8-9,

bridging paragraph). Watkins discloses that all stored raw data are associated with

metadata and are transformed into binary files (col. 13-14). Watkins discloses that raw

data comprises files organized according to explicit index (data are associated with an

object; metadata stores a basic object attribute, (col. 12-13, bridging paragraph; col. 9,

Database Tables). Watkins discloses querying a database by a user wherein metadata is

stored in a database (col. 14, line 39-41). Watkins discloses raw data comprising multiple

files and raw data converted into a single binary file and multiple binary files (*see* col.

13). Watkins discloses a menu comprising text form from metadata file (col. 13 and fig.

13-16). Watson discloses a tree-structured data (*e.g.*, multiple versions of hierarchy

(configuration management), a parent-child database) (col. 9, line 64 – col. 10. line 32).

It would have been obvious to one skilled in the art at the time of the invention to

modify the method and the system of Fink to use metadata files and binary files and

reference metadata to convert raw data into a binary file, such as taught by Watkins,

where the motivation would have been to improve selecting and viewing data, as taught

by Watkins, col. 1, line 10-32 and col. 13, line 1-62.

Claims 1-2, 4-22, 24-26, and 28 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Herren, U.S. Patent 6,108,635, in view of Watkins, U.S. Patent

6,457,017.

Herren discloses an integrated disease information system and a method for

developing new therapies. The method comprises steps of receiving raw data generated

by a model (col. 7, line 64-67; col. 18-19 table 3), extracting index information (claim 1),

generating a graphical user interface (col. 5, line 56-62 and fig. 9, 12-14), presenting a

menu to a user (fig. 9, 12, 13-14), receiving a use selection (claim 1), identifying a subset

of data relevant to the user selection and presenting data (claims 1-2 and fig. 9, 12-14).

Herren discloses subsets representing a clinical effect (claims 1-2). Herren discloses

independent variables (col. 19, line 15-36). Herren discloses independent variables

required for a clinical effect (col. 26, 48-60 and fig. 8-9). Herren discloses table, matrix

of tables, plot, and matrix of plots presentation formats (fig. 9, 12-13, 16-18). Herren

discloses a contrast between a drug candidate and its competitor (*e.g.*, a standard, fig. 13).

Herren discloses data representing contrast between output corresponding to two

controllable variable input scenarios and specifically where the contrast is a difference.

(col. 27, line 5-15; fig. 9; col. 22, line 28-47). Specifically, Heren discloses comparing a

proposed intervention with a standard intervention (col. 8, line 2-24; col.4, line 22-41).

Herren discloses input selected from an endpoint, a controllable variable, and

uncontrollable variable (col. 19, line 15-36 and col. 22, line 32-47; col. 30, line 60-64). Herren discloses an uncontrollable variable comprises a model assumption (col. 7, line 64 – col. 8, line 2). Herren discloses a system for performing his method (fig. 1-2).

Herren does not disclose metadata files, binary files, and converting raw data onto a binary file by referencing a metadata file.

Watkins discloses an information management system. Watkins' system has an object-oriented architecture over a relational database in order to manage files of information wherein files are indexed and can be retrieved (*see* abstract). Watkins discloses a graphical user interface for displaying files content to a user (col. 11-12, *User Interface*). Watkins discloses that raw data are indexed and stored in a database and converted to a specified type of data by the system to a human-readable form (col. 8-9, bridging paragraph). Watkins discloses that all stored raw data are associated with metadata and are transformed into binary files (col. 13-14). Watkins discloses querying a database by a user wherein metadata is stored in a database (col. 14, line 39-41). Watkins discloses raw data comprising multiple files and raw data converted into a single binary file and multiple binary files (*see* col. 13). Watkins discloses a menu comprising text form from metadata file (col. 13 and fig. 13-16). Watson discloses a tree-structured data (*e.g.*, multiple versions of hierarchy (configuration management), a parent-child database) (col. 9, line 64 – col. 10. line 32).

It would have been obvious to one skilled in the art at the time of the invention to modify the method and the system of Herren to use metadata files and binary files and reference metadata to convert raw data into a binary file, such as taught by Watkins,

where the motivation would have been to improve selecting and viewing data, as taught

by Watkins, col. 1, line 10-32 and col. 13, line 1-62.

Claims 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Herren, U.S. Patent 6,108,635, in view of Watkins, U.S. Patent 6,457,017, as applied to

claims 1-2, 4-22, 24-26, and 28 above, and in view of Redlich, US 2005/0138110.

Herren and Watkins make obvious the method and the system of claims 1-2, 4-22,

24-26, and 28, as set forth above.

Herren and Watkins do not discloses binary files with n-dimensional structure.

Redlich discloses a method and a computer system for processing and securing

data. Redlich discloses graphical user interface and "interaction" between stored

information and a user (*see* [0092], [0347-35], [0404-0407]). Content data (raw data) are

connected to metadata [0350], and metadata define a content of binary files [0092].

Object information and metadata are encoded in an ordered tree structure (hierarchy

structure) with root, branch, and leaf components [0092]. An object hierarchy structure is

described as a binary tree, category structure, or hive (n-dimensional structure) [0405].

It would have been obvious to one skilled in the art at the time of the invention to

modify the method and the system of Herren and Watkins to use n-dimensional binary

files, such as taught by Redlich, where the motivation would have been to improve data

coding, storage, formatting, and presentation, as taught by Redlich, [0350], [0405] and

[0092].

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller
Examiner
Art Unit 1631

MARJORIE A. MORAN
PRIMARY EXAMINER

MM

/Marjorie Q. Moran/
8/18/05